PATENT

In re Application of:
Carson and Albani
Application No.: 09/616,247

Filed: July 14, 2000

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Attorney Docket No.: UCSD1370-5

REMARKS

A. Regarding the Amendments

Claims 10 and 18-24 have been amended as set forth in the attached "Version With Markings To Show Changes Made." New claim 32 has been added. As amended, the claims are supported by the specification and the original claims and do not add new matter. The amendments to the claims simply remove the statement of use language, deleting the reference to the intended use of the claimed compositions. The claims now read more clearly as composition claims. New claim 32, similarly, merely clarifies language deleted from claim 10. These amendments and new claim 32 were previously submitted in the Response After Final, mailed January 7, 2003, but not entered. Entry of the present amendment in connection with the RCE is respectfully requested. Upon entry of the amendments, claims 10, 18-24 and 32 will be pending.

B. Priority

It is noted in Paper No. 11 that there is a need to amend the reference to prior applications. The Examiner's attention is respectfully drawn to the amendments section above, where the "Related U.S. Patent Applications" section of the application has been amended to include the current status of all applications to which priority is claimed.

C. Specification

The specification is objected to for allegedly containing blank spaces for application serial number and filing date on page 17, line 18. The Examiner's attention is respectfully drawn to the preliminary amendment filed with the application on July 14, 2000, which requests insertion of "--08/593,554, filed January 30, 1996--" at page 17, line 18. As this blank in the disclosure was filled in as previously submitted, removal of this rejection is respectfully requested.

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D. Rejection Under 35 U.S.C. § 112

Applicants respectfully traverse the rejection of claims 10 and 18-24 under 35 U.S.C. § 112, first paragraph, as containing subject matter allegedly not described in the specification in such a way as to enable one skilled in the art to which it pertains to make and/or use the invention. It is alleged in Paper No. 8 and reiterated in Paper No. 11 and the Advisory Action that claims 10 and 18-24 are not enabled for a DNA composition useful in inducing immune protection against arthritogenic peptides in a host comprising a recombinant gene expression vector which encodes bacterial dnaJp1 peptide.

It is respectfully submitted that patentability of the claimed invention turns on the patentability of the claimed compositions, not any statement of use. Applicants respectfully draw the Examiner's attention to the amended claims, which have been amended to remove the reference to statements of use. However, it is noted for the record that the foregoing amendments in no way limit the scope of the claimed compositions, as such compositions can be used to make the encoded polypeptides in any context. The foregoing amendments simply serve to clarify this point because, as the law makes clear, statements of use are not to be read as limitations in claims to compositions of matter.

The specification discloses the claimed polynucleotides, such that one of skill in the art would have known how to identify those polynucleotides. Because the application teaches those in the art how to make and use the invention as claimed, claims 10 and 18-24 meet the enablement requirement of 35 U.S.C. §112, first paragraph. As such, removal of the rejection is requested.

CONCLUSION

In summary, for the reasons set forth herein, Applicants maintain that claims 10, 18-24 and 32 clearly and patentably define the invention, respectfully request that the Examiner

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reconsider the various grounds set forth in the Office Action, and respectfully request the allowance of the claims which are now pending.

If the Examiner would like to discuss any of the issues raised in the Office Action, Applicant's representative can be reached at (858) 677-1456. Please charge any additional fees, or make any credits, to Deposit Account No. 50-1355.

Respectfully submitted,

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Date: May 13, 2003

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

N THE SPECIFICATION:

The paragraph following the heading "Related U.S. Patent Applications" has been amended as follows:

This <u>application</u> is a divisional of U.S. Patent Application Serial No. 09/107,615, filed June 30, 1998, <u>now U.S. Patent No. 6,153,200</u> [(allowed)], which is a divisional of U.S. Patent Application <u>Serial No.</u> [08/618,064] <u>08/618,464</u>, filed March 15, 1996, now U.S. Patent No. 5,773,570, which is a continuation in part of U.S. Patent Application Serial No. 08/246,988, filed May 20, 1994, now abandoned, <u>all of which are hereby incorporated by reference in their entirety</u>.

- 10. (Currently Amended) [A] An isolated polynucleotide [composition useful in inducing immune protection against arthritogenic peptides in a host comprising a recombinant gene expression vector] which encodes bacterial dnaJp1 peptide having the amino acid sequence of SEQ ID NO: 4.
- 18. (Currently Amended) The <u>polynucleotide</u> [composition] of claim [10] <u>32</u>, wherein the recombinant gene expression vector further encodes at least one dnaJ polypeptide other than dnaJp1 peptide.
- 19. (Currently Amended) The <u>polynucleotide</u> [composition] of claim 18, wherein the dnaJ polypeptide is found in a human dnaJ protein.
- 20. (Currently Amended) The <u>polynucleotide</u> [composition] of claim [10] <u>32</u>, further comprising a recombinant gene expression vector which encodes at least one dnaJ polypeptide other than dnaJp1 peptide.

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- 21. (Currently Amended) The <u>polynucleotide</u> [composition] of claim 20, wherein the dnaJ polypeptide is found in a human dnaJ protein.
- 22. (Currently Amended) The <u>polynucleotide</u> [composition] of claim 10, wherein the dnaJp1 peptide is produced by bacteria selected from at least one of the genera consisting of Escherichia, Lactococcus, Klebsiella, Proteus, and Salmonella.
- 23. (Currently Amended) The <u>polynucleotide</u> [composition] of claim 10, further comprising an immunomodulatory compound.
- 24. (Currently Amended) The <u>polynucleotide</u> [composition] of claim 23, wherein the immunomodulatory compound is transforming growth factor- β (TGF- β).